

**FEDERAL ELECTION COMMISSION****Clearinghouse on Election Administration; Notice of Meeting**

In accordance with the provisions of the Federal Advisory Committee Act (5 U.S.C. App. I) and Office of Management and Budget Circular A-63, as revised, the Federal Election Commission announces the following Advisory Panel meeting.

*Name:* Federal Election Commission Clearinghouse Advisory Panel.

*Date:* 4-5 August 1995.

*Place:* The ANA Westin Hotel 2401 M Street NW., Washington DC 20037.

*Time:* 0900-1200; 1300-1500 on 4 August 1995, 0900-1200 on 5 August 1995.

*Proposed Agenda:* Clearinghouse priorities in information and research services, plans for database development, and report on current research efforts. Open discussion.

*Purpose of the Meeting:* The Panel will present their views on problems in the administration of Federal elections, and formulate recommendations to the Federal Election Commission Clearinghouse for its future program development.

The Advisory Panel meeting is open to the public, dependent on available space. Any member of the public may file a written statement with the Panel before, during or after the meeting. To the extent that time permits, the Panel Chairman may allow public presentation or oral statements at the meeting.

All communications regarding the Advisory Panel should be addressed to Penelope Bonsall, National Clearinghouse on Election Administration, Federal Election Commission, 999 E Street NW Washington DC 20463.

Dated: April 13, 1995.

**Marjorie W. Emmons,**

*Secretary to the Commission.*

[FR Doc. 95-17612 Filed 7-17-95; 8:45 am]

BILLING CODE 6715-01-M

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 1, 1995.

**A. Federal Reserve Bank of Richmond** (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *FCNB Corp.*, Frederick, Maryland; to acquire Laurel Bancorp, Inc., Laurel, Maryland, and indirectly acquire Laurel Federal Savings Bank, Laurel, Maryland, and thereby engage in acquiring a savings and loan holding company and its subsidiary federal savings bank, pursuant to § 225.25(b)(9) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, July 12, 1995.

**Jennifer J. Johnson,**

*Deputy Secretary of the Board.*

[FR Doc. 95-17558 Filed 7-17-95; 8:45 am]

BILLING CODE 6210-01-F

**FEDERAL RESERVE SYSTEM****FCNB Corp.; Acquisition of Company Engaged in Permissible Nonbanking Activities**

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 1, 1995.

**A. Federal Reserve Bank of Minneapolis** (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Peter J. Mehlhaff*, Sioux Falls, South Dakota; to acquire an additional 47.87 percent, for a total of 70.22 percent, and Patrick O. Mehlhaff, Eureka, South Dakota, to acquire an additional 14.98 percent, for a total of 29.78 percent, of the voting shares of Great Plains Bank Corporation, Eureka, South Dakota, and thereby indirectly acquire Eureka State Bank, Eureka, South Dakota and First National Bank of Eden, Eden, South Dakota.

Board of Governors of the Federal Reserve System, July 12, 1995.

**Jennifer J. Johnson,**

*Deputy Secretary of the Board.*

[FR Doc. 95-17559 Filed 7-17-95; 8:45 am]

BILLING CODE 6210-01-F

**Olympia Bancorporation, Inc. Employee Stock Ownership Plan, et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies**

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

**Peter J. Mehlhaff, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies**

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal

Unless otherwise noted, comments regarding each of these applications must be received not later than August 11, 1995.

**A. Federal Reserve Bank of Chicago**  
(James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Olympia Bancorporation, Inc. Employee Stock Ownership Plan*, Chicago Heights, Illinois; to become a bank holding company by acquiring 50.01 percent of the voting shares of Olympia Bancorporation, Inc., Chicago Heights, Illinois, and thereby indirectly acquire Heritage Olympia Bank, Chicago Heights, Illinois.

**B. Federal Reserve Bank of Dallas**  
(Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *FCT Bancshares, Inc.*, Mart, Texas; to become a bank holding company by acquiring 100 percent of First Central Holdings, Inc., Dover, Delaware, and thereby indirectly acquire The First National Bank of Mart, Mart, Texas.

In connection with this application, First Central Holdings, Inc., Dover, Delaware; also has applied to become a bank holding company by acquiring 100 percent of the voting shares of The First National Bank of Mart, Mart, Texas.

Board of Governors of the Federal Reserve System, August 12, 1995.

**Jennifer J. Johnson,**

*Deputy Secretary of the Board.*

[FR Doc. 95-17560 Filed 7-17-95; 8:45 am]

BILLING CODE 6210-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 95N-0200]

#### Public Hearing: Products Comprised of Living Autologous Cells Manipulated ex vivo and Intended for Implantation for Structural Repair or Reconstruction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public hearing to discuss the regulation of products that are comprised of living autologous cells manipulated ex vivo and intended for implantation for structural repair or reconstruction of the source tissue or other tissue, including products used for cosmetic reconstruction and augmentation. The products to be discussed at this hearing are described in further detail in this document.

In view of the emergence of new autologous cell products and the potential enhancement to the public health, the purpose of the hearing is to solicit information and views from interested persons, including scientists, clinical investigators, professional groups, trade groups, commercial enterprises, and consumers, on the issues and concerns relating to regulation of such products.

Preregistration by written notice is advised to ensure participation. The procedures governing the hearing are found in 21 CFR part 15.

**DATES:** Submit written notices of participation by October 26, 1995. The public hearing is scheduled for November 16 and 17, 1995, from 9 a.m. to 5 p.m. Written comments will be accepted until February 16, 1996.

**ADDRESSES:** The public hearing will be held at the Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD 20877, 301-977-8900. Submit written notices of participation and comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Transcripts of the hearing also will be available for review at the Dockets Management Branch.

#### FOR FURTHER INFORMATION CONTACT:

Andrea E. Chamblee, Office of the Commissioner (HF-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1306.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Over the last several years, FDA has worked to clarify its approach to the regulation of products that are comprised in whole or in part of living cellular materials. The agency's approach has been embodied in several recent policy statements. The agency's statement on somatic cell therapy was published in a notice in the **Federal Register** of October 14, 1993 (58 FR 53248). The agency's position on banked human tissue was outlined in an interim rule published in the **Federal Register** on December 14, 1993 (58 FR 65514).

As noted, the agency described its policies for the regulation of somatic cell therapies in an October 1993 notice. The somatic cell statement defined

somatic cell therapy products as autologous (i.e., self), allogeneic (i.e., intra-species), or xenogeneic (i.e., inter-species) cells that have been propagated, expanded, selected, pharmacologically treated, or otherwise altered in biological characteristics ex vivo (i.e., outside the body) to be administered to humans and applicable to the prevention, treatment, cure, diagnosis, or mitigation of disease or injuries. FDA defined "manipulation" as the ex vivo propagation, expansion, selection, or pharmacological treatment of cells, or other alteration of their biological characteristics.

The statement outlined the regulatory controls over somatic cell therapy products, and explained that the degree of regulatory control reflected the extent and intent of cell processing ex vivo. Thus, in accordance with the statement, cells manipulated in a way that changed the biological characteristics of the cell population would be subject to product licensure as final biological products. The statement also made clear that such products would be subject to all other pertinent regulatory requirements, including provisions governing drug listing and registration, and rules governing misbranding and adulteration.

In contrast, the October 1993 notice on somatic cell products stated that applications for premarket approval were not presently required for certain other cellular products, including minimally manipulated or purged bone marrow, and certain minimally processed cell transplants.

The statement also indicated that the field of somatic cell therapy was dynamic and rapidly expanding, and stated that, "[a]s scientific knowledge in the area of somatic cell therapy continues to accumulate and evolve, the agency's approach may also evolve" (58 FR 53248). The agency also acknowledged the need to reconsider periodically its approach to these evolving products in an article by FDA's Commissioner David Kessler, entitled "Regulation of Somatic-Cell Therapy and Gene Therapy by the Food and Drug Administration" that published in the *New England Journal of Medicine* on October 14, 1993. That article observed that, "[a]s these novel therapeutic applications are explored and knowledge about risks and benefits accumulates, the FDA's regulatory approach may be modified."

In the **Federal Register** of December 14, 1993 (58 FR 65514), FDA established certain requirements for banked human tissue intended for transplantation. Banked human tissue products are described in the interim final rule as